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TITLE

HEARING TEST APPARATUS AND METHOD HAVING
AUTOMATIC STARTING FUNCTIONALITY

CROSS-REFERENCE TO RELATED APPLICATIONS

N/A

**STATEMENT REGARDING FEDERALLY SPONSORED
RESEARCH OR DEVELOPMENT**

N/A

BACKGROUND OF THE INVENTION

Hearing test devices that monitor the condition within a human ear are known. Such test devices generally require that the person performing the test (the "operator") place a test probe of the device within the ear canal of a test subject. Once the probe is placed properly within the ear canal, the operator activates the device, usually by pressing a button or the like. The device then emits test signals into the subject's ear through the probe in the ear canal. In response to the test signals emitted, the device receives response signals from the ear, likewise through the probe in the ear canal. Such response signals received are then used to determine whether the ear is functioning properly.

One such test device analyzes the distortion product otoacoustic emissions (DPOAE) generated by the ear to determine middle ear function. More specifically, a DPOAE test device generates and emits two audible tones (i.e., test signals) at different frequencies into the ear canal of a subject. A healthy ear will produce, in response to the two audible tones, a response signal having a frequency that is a combination

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In addition, DPOAE test devices also generally modify the frequencies of the audible tones transmitted into the ear canal over time during the course of the test. In response, a healthy subject's ear will emit a distortion product having a frequency that similarly changes over time during the course of the test. Generally speaking, the lack of distortion product otoacoustic emissions from the ear during the course of the test is an indication of possible hearing loss.

Existing DPOAE test devices all use a probe that is inserted into the ear canal of the test subject. Such a probe is either attached to the device via a cable, or is mounted on the device to form an integrated hand-held device. In either case, proper placement of the probe into the ear canal is critical to obtaining accurate and useful DPAOE measurements. This is primarily due to the fact that otoacoustic emissions produced by a healthy ear are extremely small in magnitude, typically in the range from -10dB SPL to $+20\text{dB SPL}$. Improper placement of the test probe in the ear canal may result in the inadvertent masking of the emissions (and thus the triggering of a false negative response), in an inaccurate measurement, or in an otherwise invalid result.

Proper placement of the test probe in the ear canal is generally determined by one or more of several factors. An operator may be required to insert the probe deeply into the ear canal and/or to create a seal between the probe and the ear canal. An operator may also be required to ensure that the probe is not blocked by a collapsed ear canal, by the canal wall itself, or by earwax. In addition, the operator may also

be required to determine that, once the probe is inserted, the resulting volume of the ear canal is within a certain desirable range.

Consequently, it is often very difficult for an operator to know whether proper placement of the probe has been achieved before the operator initiates the testing process. Moreover, particularly in the case of an integrated hand-held device, the act of initiating the test (e.g., pressing a start button) may shift the placement of the probe in the ear canal, which in and of itself may cause an inaccurate measurement. As a result, an operator may be required to perform several tests in order to obtain accurate measurements, greatly slowing down the testing process.

In addition, in some cases, these problems may prevent an accurate measurement altogether. Specifically, a large proportion of DPOAE testing is performed on infants. Typically, the infant is asleep when the testing is performed so that movement (and thus noise) is minimal. The process of properly placing and positioning the probe into an infant's very small ear canal for the amount of time and number of iterations needed to obtain accurate results often wakes the infant, which often makes the test impossible to complete, particularly if the infant is crying.

Therefore, it is an object of the present invention to provide a test operator with an indication that the testing probe is properly placed within the test subject's ear canal.

It is also an object of the present invention to provide automatic initiation or starting of the test once the probe has been properly placed within the test subject's ear canal.

SUMMARY OF THE INVENTION

These and other objects of the invention are achieved in a hearing test device that transmits pre-hearing test condition analysis stimuli into the ear canal of a test subject. The device analyzes signals

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received from the ear canal in response to the stimuli, and determines from the stimuli a condition or conditions related to the position of the testing probe in the ear canal. If the condition or conditions are satisfied, the device automatically begins a hearing test. Satisfaction of the condition or conditions as such generally indicates that the testing probe is placed properly in the ear canal.

In one embodiment, the condition comprises a temporal stability condition, which is a measure of the stability of the testing probe in the ear canal. If it is determined that the testing probe is stable (i.e., stationary for a period of time) in the ear canal, the temporal stability condition is satisfied.

In another embodiment, the condition comprises a spectral response condition, which is a measure of the seal of the testing probe and of the volume of the ear canal. If it is determined that the testing probe is sealed in the ear canal and the volume of the ear canal is within an acceptable range, the spectral response condition is satisfied.

In yet another embodiment, the condition comprises a channel balance condition, which is a determination of whether any blockages exist in the sound delivery system. If a response is not received to one of the stimuli, then a blockage is assumed. If the responses received are within an acceptable range, then the condition is satisfied.

The hearing test device also includes a display that provides an indication of the volume behind the testing probe, as well as the noise being received by the device, to assist the operator in properly positioning the testing probe in the test subject's ear canal.

These and other advantages and novel features of the present invention, as well as details of an illustrated embodiment thereof, will be more fully understood from the following description and drawings.

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**BRIEF DESCRIPTION OF THE SEVERAL VIEWS
OF THE DRAWING**

Fig. 1 illustrates an integrated, hand-held hearing test or screener device built in accordance with the present invention.

Fig. 2 is a block diagram of a hearing test or screener device built in accordance with the present invention.

Fig. 3, is a flow chart illustrating generically the auto-start feature of the present invention.

Fig. 4 is a flow chart illustrating the auto-start feature of the present invention, in which tests are performed to analyze four pre-start conditions, namely, temporal stability, low frequency roll-off, noise limit, and channel balance.

Fig. 5 depicts screens that illustrate, via bar graph, volume and noise levels measured by the device.

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DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates an integrated, hand-held hearing test or screener device built in accordance with the present invention. The device 1 includes a housing or terminal portion 3, an isolation body or assembly 5 and a testing probe 7. The testing probe 7 includes an ear tip 9, which may be made of an elastic material, such as, for example, rubber. The testing probe 7 is integrated with the terminal portion 3 via the isolation body 5, which elastically couples or suspends the testing probe from the terminal portion 3. Additional detail regarding the isolation body 5 can be found in copending U.S. patent application Serial No. 09/285,938 filed April 2, 1999, which application is incorporated herein by reference in its entirety. While the testing probe 7 is illustrated in Fig.1 as being integrated with the terminal portion 3, the testing probe 7 may be separate from the terminal portion 3 and connected to the terminal portion 3 via a cable (not shown). In addition, the device 1 itself may also be a stationary (i.e., not hand-held) device having a probe connected thereto via a cable, as is known in the art.

Referring again to Fig.1, the terminal portion 3 includes a handle portion 11, a keyboard 13 and a display 15, which may be, for example, an LCD display. An operator grasps the handle portion 11, and manipulates the keyboard 13 with the operator's thumb (or forefinger). The operator may view the display 15 before, during and after the test. The terminal portion 3 also includes a data port (not shown) located on an underside of the handle portion 11. The data port enables the device 1 to be communicatively coupled to an external device, such as, for example, a personal computer, for download of test and related data or upload of programming or other information. The terminal portion 3 may also include additional visual indicators 19 (besides the display 15), such as, for example, light emitting diodes (LEDS), for indicating to the

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operator, for example, test status or the like. In Fig. 1, visual indicators 19 illustrate a "ready" status, a "test" status, and an "error" condition.

To perform a test, an operator grasps the handle portion 11 of the terminal portion 3 and moves the device 1 towards a test subject's ear (not shown). The operator then places the testing probe 7 into the subject's ear such that the ear tip 9 is seated within the subject's ear canal.

As explained more completely below, a pre-test condition analysis is initiated that determines whether certain condition(s) are satisfied, indicating that the testing probe is properly placed in the ear. Such analysis may be initiated automatically when the device is activated, or, automatically or by the operator when the testing probe 7 is placed in the subject's ear. In any case, if all condition(s) are satisfied, the actual ear test is automatically started by the device 1, without requiring operator input.

Fig. 2 is a block diagram of a hearing test or screener device built in accordance with the present invention. The block diagram of Fig. 2 is one embodiment of the device 1 of Fig. 1, which may be used, for example, to perform DPOAE testing, as discussed above. Of course, other embodiments exist that may not incorporate all of the components shown in Fig. 2, or that may incorporate components that are different than, or components in addition to, those shown in Fig. 2.

The embodiment of Fig. 2 will now be discussed with reference to DPOAE testing. A digital signal processor (DSP) 21 generates digital signals representative of two audio tones of different frequencies and transmits the digital signals to a CODEC block 23 (i.e., an analog to digital and digital to analog converter), which converts the digital signals to electrical signals. The electrical signals are transmitted to an audio source 25, which may be, for example, located in the testing probe 7 of Fig. 1. The audio source 25 may comprise, for example, two audio

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speakers. The two audio speakers respectively transduce electrical signals into audible tones that are transmitted into the ear canal of a test subject. A microphone 27, which may, for example, be located in the testing probe 7 of Fig. 1, receives responsive audio signals from the ear of the test subject, and transduces the received audio signals into electrical signals representative of the received audio signals. The electrical signals are amplified by a microphone preamplifier 29, converted into digital signals by the block 23, and then communicated to the DSP 21. The DSP 21 then uses the signals to perform DPOAE analysis as is known in the art.

The DSP 21 also communicates output signals to the LCD Display Driver 31 which causes display of output data on the liquid crystal display 33 and/or indication of test status on visual indicators (e.g., LEDs) 35. In general, the output data comprises, for example, test results or the like. Output data, as such, may be displayed before, during and after the test. In fact, as discussed more completely below, the display may be used by an operator before the test to assist in properly placing the testing probe into the ear canal.

An operator may also use a headphone to further assist with proper placement of the testing probe in the ear. In one embodiment, the DSP 21 communicates digital signals (e.g., representative of the audio signals received from the ear) to a D/A converter 37 which converts the digital signals into electrical signals. The electrical signals are then amplified by the amplifier 39 and communicated to a headphone output 41. The headphone output 41, which may be, for example, headphone jack 17 shown in Fig. 1, is connected to a headphone assembly (not shown), which transduces the electrical signals into audio signals. Alternatively, the headphone output may be located adjacent the data port on the underside to the handle portion 11. With such a configuration, an operator may, for example, monitor the audio signals

received from the ear to assist in the positioning and repositioning of the probe within the ear canal. Additional detail regarding audibly monitoring the condition in the ear can be found in copending U.S. patent application Serial No. 08/971,520 filed November 17, 1997, which application is incorporated herein by reference in its entirety.

In a further embodiment, discussed more completely below, the DSP 21 communicates status signals, to the headphone output 41, which signals can be audibly monitored by an operator via the headphones, to assist with the positioning of the probe within the ear canal.

The DSP 21 also downloads or uploads data via the data port by communication with the RS-232 driver 43. In addition, keypad 44 enables an operator to enter data and/or commands into the device 1.

As mentioned above, the actual testing phase performed by the testing device is automatically started after the testing probe has been placed in the ear canal and upon the completion of a pre-test condition analysis. In other words, the device does not begin the actual test until it determines that the testing probe has been properly placed in the ear canal.

Such auto-start functionality simplifies the testing procedure. Since the actual hearing test begins once it is determined that the probe is properly placed in the ear canal and without requiring further action by the operator, there is a greater chance that accurate data will be generated by the first hearing test attempt. As mentioned above, this is particularly important for infants, who are most often tested while they are sleeping. In addition, such auto-start functionality eliminates the potential movement problems associated with the operator pressing a button to initiate a test while the probe is in the subject's ear. This is particularly true for a hand-held device such as that shown in Fig.1, since the action of depressing a key often results in inadvertent probe movement.

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Fig. 3, is a flow chart illustrating generically the auto-start feature of the present invention. The functionality of Fig. 3 may be implemented using a digital signal processor. As mentioned above, the auto-start feature of the present invention involves a pre-hearing test condition analysis. The analysis begins by application of a series of stimuli to the subject's ear (block 45) by a source, such as, for example, a speaker. A receiver, such as, for example, a microphone receives responsive signals from the ear, which are measured both over time and frequency. The measured signals are then used to perform one or more tests (blocks 47, 49, 51) to determine whether certain condition(s) exist (or do not exist, as the case may be) that indicate proper placement of the probe within the ear canal. If any one of the tests are failed (or if the single test is failed if only one test is being performed), the process begins over again by application of the stimuli at block 45. If, however, all of the tests are passed (or if the single test is passed if only one test is being performed), indicating that the proper condition(s) are present, the actual hearing test (e.g., a DPOAE test) is automatically initiated (block 53).

Fig. 4 is a flow chart illustrating the auto-start feature of the present invention, in which tests are performed to analyze four pre-start conditions, namely, temporal stability, low frequency roll-off, noise limit, and channel balance. The functionality of Fig. 4 may be implemented by the hearing test or screener device of Figs. 1 and 2.

The analysis begins by the application of stimuli to the ear canal (block 55) via the source or speakers 25 of Fig. 2. As discussed above, the stimuli is generated by the DSP 21 of Fig. 2. Such stimuli may, for example, be alternating 300 Hz and 1KHz audio tones. Such stimuli may also be non-audio stimuli. The microphone 27 receives responsive signals from the ear which are measured over time by the DSP 21 and used to perform condition tests.

Referring to block 57 of Fig. 4, if it is determined that the probe is unstable, the temporal stability condition test begins over again at block 55. If, however, it is determined that the probe is stable, the next test is initiated. Additional detail regarding determining the temporal stability condition is set forth below.

Referring to block 59 of Fig. 4, if it is determined that the response exhibits low frequency roll-off, the process begins over again at block 55. If, however, it is determined that low-frequency roll-off is

sufficiently absent from the response, the next test is initiated. Additional detail regarding determining the spectral response condition is set forth below.

The next test performed is determining whether any background noise is received along with the response from the ear (block 61). The general purpose of this test is to delay the starting of the hearing test if there is significant background noise present. A noise floor of the response may be determined from a frequency band where there is no stimuli energy. In one embodiment, the noise floor is calculated at the lowest frequency to be tested. When the noise floor is below an acceptable level, the test is passed. In general, if the noise level is too high, for example, if there is background noise in the test room or if the test subject is swallowing or coughing, the actual hearing test is delayed. Otherwise, the unwanted noise may mask the signals needed to perform the actual hearing test.

Referring to block 61 of Fig. 4, if it is determined that the noise floor is above the limit, the process begins over again at block 55. If, however, it is determined that the noise floor is below the limit, the next test is initiated.

The next test performed is determining the channel balance condition, i.e., whether any blockages exist in the sound delivery system (block 63). A set of stimuli is applied in an alternating fashion by the sound source (e.g., two speakers), and the response received from the ear canal is measured. If one of the responses is not received, then it is assumed that a blockage exists. In general, this test is passed when the responses received as a result of each speaker are within an acceptable range.

Referring to block 63 of Fig. 4, if the responses are not within an acceptable range, it is assumed that the channels are unbalanced and the process begins over again at block 55. If, however, the responses are

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the microphone 27 of Fig. 2). Such auditory queues may be presented to the operator via external headphones, as discussed above with respect to Fig. 2, and may comprise distinctive sounds for each condition test performed during the auto-start phase.

While Fig. 4 shows four condition tests being performed, it should be understood that any number of those tests can be implemented in any given system. For example, following this description and prior to the claims is 6 pages of an exemplary computer code listing (hereinafter referred to as "the Code") in which only the condition tests of blocks 57, 59 and 63 of Fig. 4, namely, the temporal stability condition test, spectral response condition test, and receiver balance condition test, are performed. The Code is one embodiment of the auto-start phase that may be used by the device of Figs. 1 and 2, and is being submitted as part of the specification pursuant to 37 C.F.R. §1.96(b)(2).

The auto-start phase as set forth in the Code may be described as follows. The stimuli applied to the ear canal consists of two pure tones at different frequencies (F1, F2), with one tone applied per speaker. The tones F1 and F2 may be 300Hz and 1000Hz, for example. The response is measured over a fixed interval of time. The frequency of the tones are then reversed on the speakers and the response is measured again. This complete sequence is completed at least once, resulting in each speaker sending out four tones. Specifically, this complete sequence may be illustrated as follows:

Stimuli #	Speaker A	Speaker B
n-3	F1	F2
n-2	F2	F1
n-1	F1	F2
n	F2	F1

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Figure 1

Figure 1

Figure 1

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Figure 1

Figure 1

Figure 1

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where fit_bal2 is the temporal balance parameter (in dB). The value of the temporal balance parameter, which may be, for example 2dB, establishes how closely the response at each frequency must match in order to conclude that the probe is stable.

Specifically, for speaker A, the difference between the responses for the first tone (F1) (i.e., the difference in pressure resulting from the first and third stimuli) is calculated. Also, the difference between the responses for the second tone (F2) (i.e., the difference in pressure resulting from the second and fourth stimuli) is calculated. The same two calculations are also performed for speaker B. If all four calculated values are no greater than 2dB, for example, then the temporal stability test is passed, and the conditional analysis proceeds to the spectral response condition test.

The spectral response condition test determines the difference in the response as a function of frequency, according the following equations:

$$| P2(n) - P1(n-1) | \leq \text{fit_bal3} \quad \text{Speaker A}$$

$$| P1(n) - P2(n-1) | \leq \text{fit_bal3} \quad \text{Speaker B}$$

where fit_bal3 is the spectral response parameter (in dB). In other words, the response generated by each speaker is compared at different frequencies (e.g., 300Hz v. 1000Hz) to determine if a leak in the probe seal exists. If the calculated difference between the response generated by each speaker is no greater than say, for example, 25dB, then it is assumed that no leak is present.

The spectral response condition test also determines the average receiver response to the first tone (F1) according to the following equation:

where fit_bal is the receiver balance parameter (in dB). In other words, the response generated by tone F1 is compared at each speaker, and the response generated by tone F2 is compared at each speaker. If both comparisons result in a value of no greater than 4dB, for example, then it is assumed that both speakers are functioning (e.g., neither is blocked). Once this test is passed, the actual hearing test is automatically started.

Again, in the present embodiment, all condition tests must be passed for the actual hearing test to be automatically started. If any fail, the process begins over again by the transmission of two more sets of tones are transmitted (corresponding to fifth and sixth stimuli). The responses are then reevaluated. Specifically, fifth and sixth sets of responses are generated, and they are used with the third and fourth sets of responses in performing the condition tests over again. The first and second sets of responses are discarded. If one of the condition tests is again failed, two more sets of tones are transmitted (corresponding to seventh and eighth stimuli), and seventh and eighth sets of responses are generated. They are used with the fifth and sixth sets of responses in performing the condition tests over again. The third and fourth sets responses are discarded. This process is repeated until all condition tests are passed.

As mentioned above, it may be desirable to provide the operator feedback during the auto-start phase of the testing process. The Code provides for display of data to assist the operator in positioning the probe in the ear canal. Fig. 5 depicts screens that illustrate, via bar graph, volume and noise levels measured by the device. Screen 71 shows a condition where the noise and volume are high, indicating that the probe has not yet been placed in the ear canal. Screen 73 shows a condition where the noise and volume are lower, indicating to the operator that, while the probe is being positioned in the ear canal, it has not been inserted properly (e.g., the probe is not deep enough and not

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sealed to the ear canal). Screen 75 shows a condition where the noise and volume are relatively low, indicating to the operator that the positioning is likely proper, and that the actual hearing test may be started soon. Of course, other types of outputs on the display are also possible, as mentioned above, to assist the operator.

Many modifications and variations of the present invention are possible in light of the above teachings. Thus, it is to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as described hereinabove.

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**"SUBMISSION OF COMPUTER PROGRAM LISTING
AS PART OF THE SPECIFICATION
PURSUANT TO 37 C.F.R. §1.96(b)(2)**

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F1seal      equ      300.0      ; test frequency #1
F2seal      equ      1000.0     ; test frequency #2
V12_Seal    equ      0.1       ; normalized seal voltage for P1 and P2 (was 0.03)

fit_bal1    equ      4.0/256.0  ; maximum difference between receiver responses
fit_bal2    equ      2.0/256.0  ; maximum retest difference for each receiver
fit_bal3    equ      25.0/256.0 ; max value for abs(P1-P2) for each receiver
fit_min     equ      32.0/256.0 ; minimum SPL/256 response for seal test
fit_max     equ      50.5/256.0 ; maximum SPL/256 response for seal test
max_seal_tries equ      60      ; number of times to try seal

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~~~~~ deleted code

; variables for autostart

; results from test (n-1)
chanA1      dc      0           ; Response at F1seal
chanB1      dc      0           ; Response at F2seal

; results from test (n)
chanA2      dc      0           ; Response at F1seal
chanB2      dc      0           ; Response at F2seal

; results from test (n-3)
chanA1old   dc      0
chanB1old   dc      0

; results from test (n-2)
chanA2old   dc      0
chanB2old   dc      0

seal_attempts dc      0

```

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; initialize variables

```
clr      a
move     a,y:chanA1old
move     a,y:chanB1old
move     a,y:chanA2old
move     a,y:chanB2old
move     a,y:seal_attempts
```

~~~~~ deleted code

fun1_loop

```
; test (n-1)    - output tone on each receiver and measure response
;              Receiver #1 - F1seal      Receiver #2 - F2seal
```

~~~~~ deleted code

; calculate P1

```
move     a1,y:chanA1
```

; calculate P2

~~~~~ deleted code

```
move     a1,y:chanB1
```

; noise bar graph

```
move     #normalized_dft_average+6,r1
jsr      dbspln                      ; A = noise power dB SPL/256.0
Hbar_Acc #NOISE_TABLE
move     #mes2a+4,r2                ; R590 put info on second line for now
jsr      move_string
```

; volume graph R590

```
move     y:chanA1,a
Hbar_Des #VOLUME_TABLE
move     #mes2a+12,r2                ; R590 put info on second line for now
jsr      move_string
```

; display message

```
move     #mes2a,r1
jsr      screen                      ; show bar graphs
```

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move    y:chanA1,a
move    y:chanB2,b
sub     b,a
move    #fit_ball1,b
cmpm    b,a

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    move    #fit_bal2,b
    cmpm    b,a
    bgt     ; retest

; channel B
    move    y:chanB1,a
    move    y:chanB1old,b
    sub     b,a
    move    #fit_bal2,b
    cmpm    b,a
    bgt     ; retest

    move    y:chanB2,a
    move    y:chanB2old,b
    sub     b,a
    move    #fit_bal2,b
    cmpm    b,a
    bgt     ; retest

    bra     fun2 ; proceed to calibration phase of test

retest

; noise bar graph
    move    #normalized_dft_average+6,r1
    jsr     dbspln ; A = noise power dB SPL/256.0
    Hbar_Acc #NOISE_TABLE
    move    #mes2a+4,r2 ; R590 put info on second line for now
    jsr     move_string

; volume graph R590
    move    y:chanB2,a
    Hbar_Des #VOLUME_TABLE
    move    #mes2a+12,r2 ; R590 put info on second line for now
    jsr     move_string

    move    #mes2a,r1
    jsr     screen ; show bar graph

    bset    #LED2,x:M_HDR
    bset    #LED3,x:M_HDR

; test for max retries
    move    y:seal_attempts,a
    add     #>1,a
```


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```
cmp      #>max_seal_tries,a
bgt      power_off
move     a,y:seal_attempts
```

; update old values

```
move     y:chanA1,a           ; save results for next pass
move     a,y:chanA1old
move     y:chanB1,a
move     a,y:chanB1old
```

```
move     y:chanA2,a           ; save results for next pass
move     a,y:chanA2old
move     y:chanB2,a
move     a,y:chanB2old
```

```
bra      fun1_loop
```

```
endsec
```

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